



## Summary of Studies Supporting USDA Product Licensure

Establishment Name	Elanco US Inc.
USDA Vet Biologics Establishment Number	303A
Product Code	4A45.20
True Name	Infectious Salmon Anemia Virus Vaccine, Killed Virus, Aeromonas Salmonicida-Vibrio Anguillarum-Ordalii-Salmonicida Bacterin
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	Forte V II - Elanco US, Inc.
Date of Compilation Summary	June 25, 2021

**Disclaimer: Do not use the following studies to compare one product to another. Slight differences in study design and execution can render the comparisons meaningless.**

<b>Study Type</b>	Efficacy
<b>Pertaining to</b>	<i>Aeromonas salmonicida</i> , <i>Vibrio anguillarum</i> , <i>Vibrio ordalii</i> , and <i>Vibrio salmonicida</i>
<b>Study Purpose</b>	To demonstrate effectiveness against furunculosis caused by <i>Aeromonas salmonicida</i> , vibriosis caused by strains of <i>Vibrio anguillarum</i> and <i>Vibrio ordalii</i> , cold water vibriosis caused by strains of <i>Vibrio salmonicida</i>
<b>Product Administration</b>	
<b>Study Animals</b>	Atlantic salmon and Coho salmon
<b>Challenge Description</b>	
<b>Interval observed after challenge</b>	
<b>Results</b>	Study data were evaluated by USDA-APHIS prior to product licensure and met regulatory standards for acceptance at the time of submission. Study data, however, are no longer available.
<b>USDA Approval Date</b>	October 4, 2001

<b>Study Type</b>	Efficacy
<b>Pertaining to</b>	Infectious Salmon Anemia Virus
<b>Study Purpose</b>	To demonstrate effectiveness against infectious salmon anemia caused by Infectious Salmon Anemia Virus.
<b>Product Administration</b>	
<b>Study Animals</b>	Atlantic salmon and Coho salmon
<b>Challenge Description</b>	
<b>Interval observed after challenge</b>	
<b>Results</b>	Study data were evaluated by USDA-APHIS prior to product licensure and met regulatory standards for acceptance at the time of submission. Study data, however, are no longer available.
<b>USDA Approval Date</b>	October 4, 2001

<b>Study Type</b>	Safety
<b>Pertaining to</b>	All fractions
<b>Study Purpose</b>	To demonstrate safety under laboratory conditions.
<b>Product Administration</b>	
<b>Study Animals</b>	Atlantic salmon
<b>Challenge Description</b>	
<b>Interval observed after challenge</b>	
<b>Results</b>	Study data were evaluated by USDA-APHIS prior to product licensure and met regulatory standards for acceptance at the time of submission. Study data, however, are no longer available.
<b>USDA Approval Date</b>	October 4, 2001